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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/762,796      | 01/22/2004  | Joseph Tucker        | 09741.0004-00000    | 5397             |

22852 7590 06/23/2006

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| EXAMINER |
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OLSON, ERIC

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| ART UNIT | PAPER NUMBER |
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1623

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/762,796 | <b>Applicant(s)</b><br>TUCKER ET AL. |  |
|                              | <b>Examiner</b><br>Eric S. Olson     | <b>Art Unit</b><br>1623              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **Detailed Action**

This application is a continuation-in-part of 10, filed August 15, 2002, and also claims benefit of provisional applications 60/509156, filed October 7, 2003, 60/510669, filed October 10, 2003, and 60/510342, filed October 10, 2003. Claims 1-20 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted December 13, 2004 is acknowledged wherein the specification is amended.

### **Restriction**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to a stilbene compound as illustrated in claim 1, classified in class 536, subclass, 16.3 and class 568, subclass 706, 710, 711, 729, and 928, for example.
- II. Claims 5 and 9, drawn to a flavonoid or isoflavonoid compound as illustrated in claim 5, classified in class 536, subclass, 16.3, class 549, subclass 403 and 426, and class 568, subclass 306, 706, 710, 711, 729, and 928, for example.
- III. Claim 13, drawn to a chalcone compound as illustrated in claim 13, classified in class 536, subclass, 16.3, class 568, subclass 306, 585, 586, 706, 710, 711, 729, and 928, for example.

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- IV. Claim 17, drawn to a polyphenol compound as illustrated in claim 17, classified in class 534, subclass 558, class 536, subclass, 16.3, and class 568, subclass 306, 706, 710, 711, 729, and 928, for example.
- V. Claims 2-4, drawn to a method of treating various conditions by administering a stilbene compound as illustrated in claim 1 to a patient, classified in class 514, subclass 25 and 657, for example.
- VI. Claim 6-8 and 10-12, drawn to a method of treating various conditions by administering a flavonoid or isoflavonoid compound as illustrated in claim 5, classified in class 514, subclass 25, 456, and 657, for example.
- VII. Claim 14-17, drawn to a method of treating various conditions by administering a chalcone compound as illustrated in claim 13, classified in class 514, subclass 25 and 657, for example.
- VIII. Claim 18-20, drawn to a method of treating various conditions by administering a polyphenol compound as illustrated in claim 17, classified in class 514, subclass 25, 617, 618, 619, 638, 648, 664, 665, and 667, for example.

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the linking group connecting the two phenyl rings differs between the various structures of groups I-IV. This leads to significant differences in the structure of the phenyl rings and

their degrees of freedom relative to one another. Additionally, the flavonoids of group II are a recognized class of biological molecules which possess specific interactions with certain biomolecules and are expected to have specific biological activities which set them apart from the compounds of the other groups. Thus the various groups possess separate and distinct core structures.

Chemical structures which are similar are presumed to function similarly, while chemical structures which are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of ***Application of Papesch*, 50 CCPA 1084, 315 F.2s 381, 137 USPQ 43 (CCPA 1963)**, and ***In re Lalu*, 223 USPQ 1257 (Fed. Cir. 1984)**, chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Thus, a reference anticipating or rendering obvious one member will not anticipate or render another obvious. This difference is illustrated by the separate classifications of the active compounds in each group. A chemical structure or name search for more than one of the aforementioned groups in a single application would be unreasonably broad and would require separate searches of the chemical literature for each group and impose an undue search burden on the Office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as recognized by their different classifications, restriction for examination purposes as indicated is proper.

Inventions V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the therapeutic methods of groups V-VII involve structurally distinct compounds with patentably distinct structures. The linking group connecting the two phenyl rings differs between the various structures of the therapeutic agents of groups V-VII. This leads to significant differences in the structure of the phenyl rings and their degrees of freedom relative to one another. Additionally, the flavonoids and isoflavones of groups VI are a recognized class of biological molecules which possess specific interactions with certain biomolecules and are expected to have specific biological activities which set them apart from the compounds of the other groups. Thus the various groups possess separate and distinct core structures.

Chemical structures which are similar are presumed to function similarly, while chemical structures which are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention.

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Note that in accordance with the holding of **Application of Papesch, 50 CCPA 1084, 315 F.2s 381, 137 USPQ 43 (CCPA 1963)**, and **In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984)**, chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Thus, a reference anticipating or rendering obvious one member will not anticipate or render another obvious. This difference is illustrated by the separate classifications of the active compounds in each group. A chemical structure or name search for more than one of the aforementioned groups in a single application would be unreasonably broad and would require separate searches of the chemical literature for each group and impose an undue search burden on the Office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as recognized by their different classifications, restriction for examination purposes as indicated is proper.

Inventions I and V, II and VI, III and VII, and IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods of claims IV-VIII could be practices with another

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therapeutic agent, including cholesterol-lowering statins such as atorvastatin, fluvastatin, lovastatin, pravastatin, or simvastatin.

The search field for a composition is non-coextensive with the search field for a method of treating a patient employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103 because a search indicating the process or method is novel or unobvious would not extend to a holding that the product is novel or unobvious whereas a search indicating that the product is known or would have been obvious would not extend to a holding that the process or method is known and would have been obvious. Note that the search is not limited to patent files. Thus an undue burden on the Office is seen for the search of all inventions herein, as discussed in the Requirement for Restriction above.

Because these inventions are distinct for the reasons given above and the search required for Groups V-VII is not required for Groups I-IV, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to



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be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103(a) of the other invention.

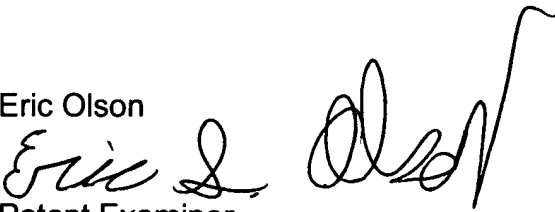
Because the above election/restriction requirement is complex, a telephone call to applicant's agent to request an oral election was not made. (See MPEP 812.01)

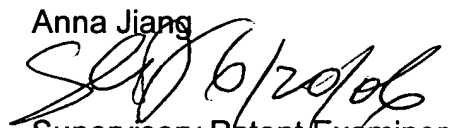
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday through Friday from 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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6/20/2006

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